

REMARKS

Upon entry of the accompanying Amendments, claim 2 will be the only claim pending in the application. In the Amendment, claims 1 and 3-7 have been canceled. Claim 2 has been rewritten into an independent form. No new matter has been introduced and entry of the amendment and reconsideration are respectfully requested.

Objection to Claim 4

Claim 4 is objected to because of the following informalities.

Applicants submit that the accompanying Amendment renders the objection moot and withdrawal of the objection is respectfully requested.

Rejection of Claims 1-4 Under 35 U.S.C. § 112, Second Paragraph

Claims 1 - 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly, the term "about 7" was pointed out and it was suggested to express the phrase "higher than or equal to about 7" by the mathematical symbol " \geq ."

Without conceding the rejection, Applicants have canceled claims 1, 3 and 4 without prejudice, solely in order to advance the prosecution. Claim 2 has been rewritten into an independent form and recites "A solid dispersion consisting essentially of tacrolimus and a solid carrier, wherein the solid carrier is at least one selected from the group consisting of sodium lauryl sulfate (HLB=40), poloxamers ($HLB \geq 7$), and sucrose fatty acid esters ($18 \geq HLB \geq 7$)."

Therefore, the rejection under 35 U.S.C. § 112, second paragraph is not sustainable and its withdrawal is respectfully requested.

Rejection of Claims 1 and 3-6 Under 35 U.S.C. § 102(b)

Claims 1 and 3 - 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hata *et al.* (US Patent 6,346,537 B1) ("Hata") as evidenced by Ueda *et al.* (Journal of Drug Targeting, 2003, 11(1), p 37 - 43).

Without conceding the rejection, solely in order to advance the prosecution of the present application, Applicants have canceled claims 1 and 3-6 without prejudice. Therefore the rejection is rendered moot and its withdrawal is respectfully requested.

Rejection of Claims 2 and 7 Under 35 U.S.C. § 103

Claims 2 and 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Hata. Applicants respectfully traverse.

Hata discloses a composition comprising (1) tacrolimus; (2) a pharmaceutically acceptable surfactant selected from the group consisting of polyoxyethylene hydrogenated castor oil, sucrose fatty acid esters, propylene glycol fatty acid mono- or di-esters, and polyoxyethylene sorbitan fatty acid esters, or a combination of two or more of these surfactants; and (3) a pharmaceutically acceptable solid carrier selected from the group consisting of water-soluble polymers, saccharides, and light anhydrous silicic acid, or a combination of two or more of these solid carrier. Claim 1 and Abstract. Accordingly, the composition taught by Hata *requires three (3) essential components*. According to Hata, the composition has improved dissolution and oral absorption characteristics.

Currently presented claim 2 recites “A solid dispersion *consisting essentially of* tacrolimus and a solid carrier, wherein the solid carrier is at least one selected from the group consisting of sodium lauryl sulfate (HLB=40), poloxamers (HLB ≥ 7), and sucrose fatty acid esters ($18 \geq \text{HLB} \geq 7$).” Therefore, claim 2 does not contain a component selected from the group consisting of water-soluble polymers, saccharides, and light anhydrous silicic acid.

The composition of the currently presented claim 2 shows *significantly improved* dissolution rates. See Examples and Table of the present application.

It is well established that the omission of an element and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966); MPEP 2144.04. (Emphasis in original).

Therefore, the subject matter of the currently presented claim 2, which shows even more improved dissolution property while it has omitted one component compared to the composition of Hata, is clearly not obvious over Hata.

Claim 7 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Hata as applied to claims 1 - 6 above in view of Patel *et al.* (US Patent 6,248,363 B1).

Without conceding the rejection, solely in order to advance the prosecution of the application, Claim 7 has been canceled without prejudice.

Accordingly, Applicants respectfully submit that the rejections under 35 U.S.C. § 103 are not sustainable and their withdrawal is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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